K130772
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510(K) Summary of Safety and Effectiveness

APR 18 2013

As required by 807.92

1. DEVICE ESTABLISHMENT AND CONTACT PERSON

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2. COMPANY REISTRATION NUMBER

3003623028

3. DATE SUMMARY PREPARED

12 October 2012

4. DEVICE NAME

Trade Name:	MD211C2 21.3" Diagnostic Imaging LCD monitor
Model Name:	MD211C2
Common Name:	Color LCD Monitor, Color Diagnostic Display, etc.
Classification Name:	System, Image Processing, Radiological (CLASS II CFR 892.2050)

4. PREDICATE DEVICE

L217TG TFT Color LCD Monitor by NEC Display Solutions Ltd. (K083907)

5. DEVICE DESCRIPTION

Medical Display, MD211C2 is a 21.3" Color LCD monitor that displays image for medical use. It provides 1.9 mega pixel (1600*1200) resolution with adjustable gamma gray scale for more precise diagnose use in CT, MRI, HIS, and PACS.

6. DEVICE OF INTENDED USE

The MD211C2 color display is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

To guarantee the display performance as specified, it must only be used for in conjunction with NEC approved display controllers.

MD211C2 cannot be used for a life-support system.

This device must not be used in digital mammography.

This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment.

7. SE Comparison Table:

Comparison tables between MD211C2 & L217TG

Items	L217TG	MD211C2
510(k) Number	K083907	
Panel Size and Type	21.3" TFT Color LCD Monitor	21.3" TFT Color LCD Monitor
Pixel Pitch	0.270 mm x 0.270 mm	0.270 mm x 0.270mm
Display Color	16.777,216	1,073,741,824
Viewing Angles (°)	H:176, V:176	H:176, V:176
Scanning Frequency (H, V)	31.5-91.1kHz , 50-85 Hz	31.5-74.5, 99.4kHz, 50-85 Hz
Native Resolutions	1600X1200	1600X1200
Brightness	400 cd/m^2 calibrated, 850 cd/m^2 Max.	400 cd/m^2 calibrated, 900 cd/m^2 Max.
Contrast Ratio	1050 : 1 (typical)	1400 : 1 (typical)
DOT Clock	162 MHz	165 MHz
Input Signals	Three connectors: one D-sub analog VGA; and two DVI-I (VGA analog or digital)	Two connectors: one DVI-D, one display port (Display port comply with standard V1.1a, applicable to HDCP

Input Terminals	DVI-D, D-sub	DVI-D, Display port
USB (option) / Standard	No	No
Active Display Size (H x V)	Landscape: 432mmX324mm Portrait: 324X432mm	Landscape: 432mmX324mm Portrait: 324X432mm
Viewable Image Size	540 mm (diagonal)	540 mm (diagonal)
Luminance Calibration	Software	Software
Default Gamma	1.8,2.0,2.2 DICOM part 14 + off, user	1.8,2.0,2.2 DICOM part 14
Power	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz
Power Consumption	100W (Max)	88W (Max)
Power Save Mode	<2W	<2W
Dimensions (W x H x D)	W: Landscape: 467.8mm Portrait:361.6 mm H: Landscape: 434.3-584.3mm Portrait: 487.4-637.4mm D: 306 mm	W: Landscape: 467.8mm Portrait:361.6 mm H: Landscape:377.6-527.6mm Portrait:483.4-580.7mm D: 227.6 mm
NET Weight	10.7 kg	11.8 kg
Intended of use	Displaying and viewing of digital images for diagnosis by trained physicians This device can not use for a life support system. This device must not be use in digital mammography. This device is designed for exclusive interconnection with IEC60601-1-1certified equipment	Displaying and viewing of digital images for diagnosis by trained physicians This device can not use for a life support system. This device must not be use in digital mammography. This device is designed for exclusive interconnection with IEC60601-1-1certified equipment
Certifications & Standards	CE ITE/Medical Device Directive, UL/cUL (UL60601-1, CSA C22.2 No.601-1), FCC Class B, EN60601-1-2, DIN V 6868-57, DICOM	CE ITE/Medical Device Directive, UL/cUL (ANSI/AAMI ES 60601-1:2005), FCC Class B, EN60601-1-2, DIN V 6868-57, DICOM

8. CONCLUSION

These two devices have the same target population of trained practitioner in hospital; it shares the same design, same performance and is the same in radiation safety (EN60601-1-2), mechanical safety, electrical safety (AAMI/ES 60601-1) human factors and DICOM conformance. It use similar material, and have same compatibility with environment and other device. Comparison table of the principal characteristics of two devices is shown in the Section 3, table 3.3. These two devices also have the same intended use; Therefore we concluded that it is substantially equivalent to L217TG by NEC Display Solutions Ltd. (K083907)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 18, 2013

NEC Display Solutions, Ltd.
% Mr. Jeffrey D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
RESEARCH TRIANGLE PARK NC 27709

Re: K130772
Trade/Device Name: MD211C2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 6, 2013
Received: April 3, 2013

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130772

Device Name: Medical Display, MD211C2

Indications for Use:

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This device must not be used in digital mammography.

This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130772